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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/990,955 | 11/16/2001 | Mitradev Boolell | PCS10382ARTB | 2910 |

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| EXAMINER | |
|---|---|
| KWON, BRIAN YONG S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | 5 |

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application N . | Applicant(s) | |
|---|---|---|---|
| | 09/990,955 | BOOLELL, MITRADEV | |
| | Examiner | Art Unit | |
| | Brian S Kwon | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-10* is/are rejected.

7)☐ Claim(s) *9-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The ~~specification~~ disclosure is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Summary of Action*

I. The amendment filed August 14, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure.

II. Claims 9 and 10 are objected.

III. Claims 1-7 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

IV. The rejection of claims 1-8 and 11 under 35 USC 102(e) as being anticipated by Lee et al. (US 6512002 B2) will not be maintained in light of the amendment.

V. The rejection of claims 1-7 and 9-10 under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (US 6403597 B1) will be maintained for the reason of record.

VI. The rejection of claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Doherty, Jr. et al. (US 6037346 A), if necessary, and further in view of Crenshaw et al. (US 5276042) and Crenshaw et al. (US 5151448) and/or Bick (US 4940731) will not be maintained in light of the amendment.

### *Response to Amendment*

1. The amendment filed August 14, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "without co-administration of an estrogen agonist/antagonist".

Applicant is required to cancel the new matter in the reply to this Office Action.

### *Claim Objections*

2. Claims 9 and 10 are objected, as being of improper dependent form for the cancelled claim (claim 8).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection of claims 1-8 and 11 under 35 USC 102(b) as being anticipated by Lee et al. (US 6512002 B2), applicants amended the claims. Newly amended claims now recite that an estrogen agonist/antagonist is not co-administered. Applicants state in page 4, lines 21-27 of Amendment/Remarks filed August 14, 2003: "Applicants submit that this amendment is fully supported. Support for this amendment may be found in claim 1 as originally filed. In addition, Applicants submit that the literal basis for such amendment is not required to be found in the specification (the claims phrase need not be "in haec verba" in the specification

In Re Wright 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989); Crowne Operations, Int'l, Inc. v. Solutia, Inc. 289 F.3d 1367, 1376 (Fed. Cir.2002)".

Applicant is correct that in order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba ("in the same words") support for the claimed subject matter in the claims. However, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. In other words, when the applicant adds a claim or otherwise amends his specification after the original filing date, the new claims or other added material must find support in the original specification.

The examiner determines that when all evidences in the original disclosure are considered and carefully reviewed, the newly amended claims fail to find support in the original specification as followings.

The specification discloses that as an embodiment of the invention, the PDE5 inhibitors can be combined with one or more additional active agents for the treatment of PD in patients with normal erectile function (page 16, lines 14-16). In addition, the specification provides examples of various suitable agents for the claimed invention including estrogen agonist/antagonist (page 16, line 14 thru page 19, line 15). Specifically in page 17, lines 25-29, raloxifene or lasofoxifen and (-)-cis-6-phenyl-5-{4-(2-pyrrolidin-1-yl-ethoxy)-phenyl}-5,6,7,8-tetrahydronaphthalene-2-ol are disclosed as preferred estrogen agonists and/or estrogen antagonists.

Therefore, it would have been clear to one skilled in the art, reading the instant disclosure, that the claimed invention can be practiced with the PDE5 inhibitor in combination

with other active agents disclosed in the specification including estrogen agonist/antagonist, not excluding estrogen agonist/antagonist as newly amended claims.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> 1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1-7 and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (US 6403597 B1).

This rejection is analogous to the original rejection.

### *Response to Arguments*

5. Applicant's arguments filed August 14, 2003 have been fully considered but they are not persuasive.

Applicant's argument takes position that the claims are not anticipated since Wilson et. Al does not teach the oral administration of a PDE5 inhibitor before Applicant's priority file date of November 20, 2000. Applicants state in pages 7-8:

"Specifically, while Wilson et al. application serial number 09/888,250 filed on June 21, 2001 does disclose the oral administration of a PDE5 inhibitor for the treatment of premature ejaculation, the parent application (Wilson et al. application serial no. 09/467,094 filed December 10, 19999) does not disclose the oral administration of a PDE5 inhibitor for the treatment of premature ejaculation. Accordingly, as of December 10, 1999 the only administration method was transmucosal (e.g., buccal, sublingual, rectal) application serial no. 09/467,094 page 8, line 29- page 9, line 8. Since Applicants' application has a filing date that is prior to the earliest Wilson et al. application that teaches oral administration Wilson et al., is not an effective reference under 35 USC 102(e). This because the invention was not described in a patent that was filed prior to Applicant's invention thereof as evidenced by Applicant's November 20, 2000 priority filing date".

"Applicants note that their claim term oral is not intended to encompass the terms bucally or sublingually as evidenced by their specification page 11, lines 9-10 which recite the terms oral, buccal and sublingual in the alternative."

The term "orally" is defined as "by, with, or in, the mouth" (Webster's Revised Unabridged Dictionary 1913) and generally means "(of drugs) administered by mouth" in the art. In other words, the term "orally", given a reasonably broader interpretation, encompasses sublingual tablet and buccal dosage form disclosed in Wilson et al. application serial no. 09/467, 094 filed December 10, 1999. Therefore, the reference anticipates the claimed invention.

***Conclusion***

6. No Claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY**
**PRIMARY EXAMINER**
**GROUP 1600**